

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donald J. KYLE <i>et al.</i>	Docket No.: 379612-250US (397490)
Serial No.: 10/588,637	Confirmation No.: 9800
Filed: August 29, 2007	Group Art Unit: 1625
For: METHODS OF MAKING 3-O- PROTECTED MORPHINONES AND 3-O PROYECTED MORPHINONE DIENOL CARBOXYLATES	Examiner: Charanjit AULAKH

STATEMENT UNDER 37 CFR § 1.705(b)(2)

VIA EFS-WEB

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This statement is respectfully submitted in support of the "Application for Patent Term Adjustment Including Request for Reconsideration under 37 CFR § 1.705(b)" for the above-captioned patent application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of **1,000 days**, which may be extended or reduced based on the actual date of issuance of a patent from the above-captioned application.

The patent term adjustment on the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) that was attached to the Notice of Allowance and which is submitted herewith as Exhibit A is 491 days. That determination projected that the patent would issue on the Tuesday before the date that is 28 weeks after the April 1, 2011, mailing date of that notice (*i.e.*, October 11, 2011). A copy of the Office's calculation for that 491 days, printed from PAIR, is submitted herewith as Exhibit B. An illustration of Applicants' patent term adjustment calculation is submitted herewith as Exhibit C.

The Office's calculation is believed to be in error for the following reason:

1. A failure by the Office to calculate any B Delay/3-Year Delay (and the resulting overlap).

What follows is a statement of the facts involved specifying the correct patent term adjustment and the basis for the adjustment under 37 CFR § 1.702, including the relevant dates as specified in 37 CFR § 1.703(a)-(e) for which adjustment is sought, and the adjustment as specified in 37 CFR § 1.703(f) to which the patent is entitled. The application is not subject to a terminal disclaimer.

A. A Delay under 37 CFR §§ 1.702(a) and 1.703(a)

Applicants are entitled to one period of patent term adjustment pursuant to 37 CFR §§ 1.702(a) and 1.703(a) as follows.

1. 14-Month Delay under 37 CFR §§ 1.702(a)(1) and 1.703(a)(1)

Applicants are entitled to a period of patent term adjustment pursuant to 37 CFR §§ 1.702(a)(1) and 1.703(a)(1) ("14-Month Delay"). Applicants do not contest herein the Office's calculation shown in Exhibit B that the 14-Month Delay associated with the May 20, 2010 mailing of a Restriction Requirement is 568 days. Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. § 132 not later than 14 months after the date of August 29, 2007, when Applicants fulfilled the requirements under 35 U.S.C. § 371 (*i.e.*, by October 29, 2008). Because the Office failed to mail an action under 35 U.S.C. § 132 until May 20, 2010, Applicants are entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after the date of August 29, 2007, when Applicants fulfilled the requirements under 35 U.S.C. § 371 (*i.e.*, October 30, 2008), and ending on the date of mailing of an action under 35 U.S.C. § 132 (*i.e.*, May 20, 2010), which is 568 days.

2. Total Period of A Delay under 37 CFR §§ 1.702(a) and 1.703(a)

Thus, the total period of A Delay under 37 CFR §§ 1.702(a) and 1.703(a) is 568 days.

B. B Delay/3-Year Delay under 37 CFR §§ 1.702(b) and 1.703(b)

Applicants are entitled to a period of patent term adjustment pursuant to 37 CFR §§ 1.702(b) and 1.703(b) due to examination delay from the number of days in the period beginning on the day after the date that is three years after August 4, 2006, when the national stage for the above-captioned application commenced under 35 U.S.C. § 371(b) (*i.e.*, August 5, 2009) and ending on the date a patent issues ("B Delay/3-Year Delay"), not including several categories of exceptions stated in 35 U.S.C. § 154(b)(1)(B)(i)-(iii). Applicants disagree with the Office's determination shown in Exhibit B that the B Delay/3-Year Delay is zero days. Instead, the correct B Delay/3-Year Delay is believed to be 798 days, which is also illustrated in Exhibit C. The facts concerning the B Delay/3-Year Delay are as follows:

1. On August 4, 2006, Applicants filed the above-captioned application under 35 U.S.C. § 371 and the national stage commenced under 35 U.S.C. § 371(b) on that date.
2. On October 11, 2011, the Office projects that the patent will issue.
See Exhibit A.

The number of days in the period beginning on August 5, 2009 and ending on October 11, 2011 is 798 days. Thus, the amount of B Delay/3-Year Delay under 37 CFR § 1.703(b) is 798 days.

C. Exclusion of Overlapping Delay under 37 CFR § 1.703(f)

Applicants are not entitled to a period of patent term adjustment to the extent the periods in 37 CFR § 1.702 (*i.e.*, the A Delay and the B Delay/3-Year Delay) overlap pursuant to 37 CFR § 1.703(f) ("Overlapping Delay"). Overlapping Delay would consist of the period of time when the A Delay overlaps the B Delay/3-Year Delay. At the earliest, the Overlapping Delay would begin on the day after the date that is three years after August 4, 2006, when the above-captioned application was filed under 35 U.S.C. § 371 (*i.e.*, August 5, 2009), *see Wyeth v. Dudas*, 88 USPQ2d 1538 (D.D.C. 2008). Applicants disagree with the Office's determination shown in Exhibit B that the Overlapping Delay is zero days.¹ Instead, the correct Overlapping Delay is believed to be 289 days, which is also illustrated in Exhibit C. The facts concerning the Overlapping Delay are as follows:

1. On August 4, 2006, Applicants filed the above-captioned application under 35 U.S.C. § 371 and the national stage commenced under 35 U.S.C. § 371(b) on that date.
2. As discussed under Section B above, the first day on which B Delay/3-Year Delay began to accrue was August 5, 2009.
3. As discussed under Section A above, the final day 14-Month A Delay accrued was May 20, 2010, the date of mailing of an action under 35 U.S.C. § 132.
4. During the period beginning on August 5, 2009 and ending on May 20, 2010, inclusive, both A Delay and B Delay/3-Year Delay accrued, *i.e.*, overlapped.

The number of days in the period beginning on August 5, 2009 and ending on May 20, 2010 is 289 days. Thus, the amount of Overlapping Delay under 37 CFR § 1.703(f) is 289 days.

D. Exclusion of Applicant Delay under 37 CFR §§ 1.703(f) and 1.704

Applicants are not entitled to a period of patent term adjustment to the extent that they failed to engage in reasonable efforts to conclude prosecution of the application pursuant to 37 CFR §§ 1.703(f) and 1.704 ("Applicant Delay"). Applicants do not contest herein the Office's calculation of Applicant Delay as shown in Exhibit B.

¹ Indicated in Exhibit B after "Overlapping Days Between {A and B} or {A and C}" as "0".

Applicants do not contest herein the Office's calculation shown in Exhibit B that the Applicant Delay is 61 days with respect to the "Response to Restriction Requirement under 37 CFR § 1.142" filed by Applicants on October 20, 2010. The Applicant Delay is the number of days beginning on the day after the date that is three months after the date of mailing of the May 20, 2010, Office communication (*i.e.*, August 21, 2010) and ending on the date the "Response to Restriction Requirement under 37 CFR § 1.142" was filed (*i.e.*, October 20, 2010), which is 61 days.

Applicants do not contest herein the Office's calculation shown in Exhibit B that the Applicant Delay is 17 days with respect to the "Response to Office Communication of Notice of Non-compliant Amendment (37 CFR § 1.121) and Amendment under 37 CFR § 1.111" filed by Applicants on March 17, 2011. The Applicant Delay is the number of days beginning on the day after the date that is three months after the date of mailing of the December 1, 2010, Office communication (*i.e.*, March 2, 2011) and ending on the date the "Response to Office Communication of Notice of Non-compliant Amendment (37 CFR § 1.121) and Amendment under 37 CFR § 1.111" was filed (*i.e.*, March 17, 2011), which is 16 days.

Thus, the total period of Applicant Delay under 37 CFR §§ 1.703(f) and 1.704 is 61 days plus 16 days or 77 days.

E. Total Patent Term Adjustment

Pursuant to 37 CFR §§ 1.703(f), the total patent term adjustment is 568 days of A Delay plus 798 days of B Delay/3-Year Delay, minus 289 days of Overlapping Delay, minus 77 days of Applicant Delay, for a total of 1,000 days. Applicants further submit that the adjustment may require change if the Office's projected issue date is incorrect.

F. Conclusion

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected determination of Patent Term Adjustment be issued to reflect a patent term adjustment of 1,000 days, which may be extended or reduced based on the actual date of issuance of a patent for the above-captioned application.

Respectfully submitted,

Date: June 28, 2011

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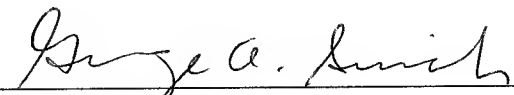

George A. Senfich
Reg. No. 42,140

Exhibit A

Copy of Determination of Patent Term Adjustment under 35 U.S.C. § 154(b)



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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,637	08/29/2007	Andreas Stumpf	379612-250US (397490)	9800
37509	7590	04/01/2011	EXAMINER	
DECHERT LLP			AULAKH, CHARANJIT	
P.O. BOX 390460				
MOUNTAIN VIEW, CA 94039-0460			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 04/01/2011

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 491 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 491 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Exhibit B

Printout of PTA Calculation from PAIR



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10/588,637

METHODS FOR MAKING 3-O-PROTECTED MORPHINONES AND 3-O-PROTECTED MORPHINONE DIENOL CARBOXYLATES

Patent Term Adjustments

Patent Term Adjustment

Filing or 371(c) Date:	08-29-2007	Overlapping Days Between {A and B} or {A and C}:	0
Issue Date of Patent:	-	Non-Overlapping USPTO Delays:	568
A Delays:	568	PTO Manual Adjustments:	0
B Delays:	0	Applicant Delays:	77
C Delays:	0	Total PTA Adjustments:	491

Patent Term Adjustment History Explanation Of Calculations

Number	Date	Contents Description	PTO (Days)	APPL (Days)	Start
58	04-01-2011	Mail Notice of Allowance			0
57	03-24-2011	Office Action Review			0
56	03-24-2011	Office Action Review			0
55	03-24-2011	Office Action Review			0
54	03-29-2011	Issue Revision Completed			0
53	03-29-2011	Document Verification			0
52	03-29-2011	Notice of Allowance Data Verification Completed			0
51	03-24-2011	Examiner's Amendment Communication			0
50	03-24-2011	Examiner Interview Summary Record (PTOL - 413)			0
49	03-24-2011	Allowability Notice			0
44	03-19-2011	Date Forwarded to Examiner			0
43	03-17-2011	Response after Non-Final Action		16	39
42	03-11-2011	Email Notification			0
41	03-10-2011	Mail Notice of Informal or Non-Responsive Amendment			0
40	03-04-2011	Date Forwarded to Examiner			0
39.1	03-01-2011	Informal or Non-Responsive Amendment after Examiner Action			0
39	03-01-2011	Response after Non-Final Action			0
38	12-01-2010	Electronic Review			0
37	12-01-2010	Email Notification			0
36	12-01-	Mail Non-Final Rejection			0

	2010			
35	11-26-2010	Non-Final Rejection		0
34	02-23-2009	Information Disclosure Statement considered		0
33	02-27-2009	Information Disclosure Statement considered		0
32	08-03-2010	Information Disclosure Statement considered		0
31	10-21-2010	Date Forwarded to Examiner		0
30	10-20-2010	Response to Election / Restriction Filed	61	23
29	10-20-2010	Request for Extension of Time - Granted		0
28	08-03-2010	Reference capture on IDS		0
27	08-03-2010	Information Disclosure Statement (IDS) Filed		0
26	08-03-2010	Information Disclosure Statement (IDS) Filed		0
25	05-20-2010	Electronic Review		0
24	05-20-2010	Email Notification		0
23	05-20-2010	Mail Restriction Requirement	568	9
22	05-18-2010	Restriction/Election Requirement		0
21	02-27-2009	Reference capture on IDS		0
20	02-27-2009	Information Disclosure Statement (IDS) Filed		0
19	02-27-2009	Information Disclosure Statement (IDS) Filed		0
18	02-23-2009	Information Disclosure Statement (IDS) Filed		0
17	07-08-2008	Case Docketed to Examiner in GAU		0
16	06-19-2008	PG-Pub Issue Notification		0
15	06-11-2008	Change In Power of Attorney (May Include Associate POA)		0
14	06-10-2008	IFW TSS Processing by Tech Center Complete		0
13	06-10-2008	Correspondence Address Change		0
10	04-09-2008	Application Dispatched from OIPE		0
9	08-29-2007	371 Completion Date		0
8	03-19-2008	Sent to Classification Contractor		0
7	03-19-2008	Filing Receipt		0
6	03-19-2008	Notice of DO/EO Acceptance Mailed		0
5	08-29-2007	Additional Application Filing Fees		0
4	08-29-2007	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic		0

0.5	02-04- 2005	International Filing date	0
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Exhibit C

Applicants' PTA Calculations

Applicants' Patent Term Adjustment (PTA) Calculations for Application Serial No. 10/588,637											
Prosecution History				PTO PTA Calculations (Days)			Applicants' PTA Calculations (Days)				
Actual Date	Action	Months Allowed for Reply	Reply Due Date	A Delay	B Delay/ 3-Year Delay	PTO Overlap	Applicant Delay	A Delay	B Delay/ 3-Year Delay	Overlap Calculated per Wyeth (88 USPQ2d 1538)	Applicant Delay
02/06/04	Provisional Application Filed										
02/04/05	PCT Application Filed										
08/04/06	Utility Application Filed	14	10/04/07								
04/30/07	Notice of Incomplete Application	3	07/30/07								
08/29/07	Application Complete		08/29/07				0				0
05/20/10	Restriction	3	08/20/10	568				568	289	289	
10/20/10	Election	4	02/20/11				61				61
12/01/10	Non-final Office Action	3	03/01/11	0				0	195		
03/17/11	Amendment	4	07/17/11				16				16
04/01/11	Notice of Allowance	3	07/01/11	0				0	121		
07/01/11	Issue Fee Payment (Assumed)	4	11/01/11				0				0
10/11/11	Issue Date Assumed by PTO in PTA Calculation								193		
	Column Totals			568	0	0	77	568	798	289	77
	Net Patent Term Adjustment						491				1,000
	Expiration Date With or Without PTA		2/4/2025	6/10/2026			11/1/2027				